



## DECLARATION OF CONFORMITY

for CE – marking according to Annex II  
of Medical Devices Directive 93/42/EEC

*Manufacturer:*

BTL Industries Limited  
Suite 401 Albany House  
324-326 Regents Street  
London  
W1B 3BL  
United Kingdom

The **BTL Industries Ltd.** herewith declares under its sole responsibility that the product

*Product Name:*

Combined therapy devices

*Type:*

BTL-5000 Series v1.xx

*Product Name:*

BTL-4000 Series v1.xx

*Type:*

Electrotherapy devices

*Product Name:*

BTL-06 v3.xx

*Type:*

BTL-5000 Puls v1.xx

*Product Name:*

BTL-4000 Puls v1.xx

*Type:*

Ultraound therapy devices

*Product Name:*

BTL-I2 v2.xx

*Type:*

BTL vac v1.xx

*Product Name:*

Ultraound therapy devices

*Type:*

BTL-07p v4.xx

*Product Name:*

BTL-5000 Sono v1.xx

*Type:*

BTL-4000 Sono v1.xx

*Product Name:*

Laser therapy devices

*Type:*

BTL-I0 v5.xx

*Product Name:*

BTL-2000 v5.xx

*Type:*

BTL-5000 Laser v1.xx

*Product Name:*

BTL-4000 Laser v1.xx

*Type:*

Magnetotherapy devices

*Type:*

BTL-09 v4.xx

*Risk Classification:*

Class IIb

conforms with the applicable regulation:

*Directive:*

MDD 93/42/EEC

*Quality Assurance Standards:*

ISO 13485 : 2003

*Procedural Standards:*

EN 60601-1 + A2

EN 60601-1-1

EN 60601-1-2

EN 60601-2-10

EN 60601-2-5

EN 60601-2-22

EN 60825-1

EN ISO 14971

ISO 10993-1

Date of Issue: 24<sup>th</sup> February 2004

Signature:

Place of Issue: London



**Daniela Marx**

Director of BTL Industries Limited